

REMARKS

Status of the Claims

Claims 1, 3, 5-7, 9, 10 and 12-14 are currently pending in the application. Claims 1, 3, 5-7, 9, 10 and 12-14 stand rejected. Claims 1, 3, 7, 10, 12 and 13 have been amended as set forth herein. All amendments are made without prejudice or disclaimer.

No new matter has been added by way of the present amendments. Specifically, the amendments to claims 1, 3, 7, 10, 12 and 14 are supported throughout the specification and specifically at pages 15 (vancomycin), 17 (mexiletine hydrochloride, ciprofloxacin hydrochloride), 22 (carbocisteine, gabapentin), 33 (metformin hydrochloride, ethydrionic acid disodium) and 34 (cimetidine). Reconsideration is respectfully requested.

Rejections Under 35 U.S.C. § 103(a)

Claims 1, 3, 5-7, 9, 10 and 12-14 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Pierre et al., U.S. Patent No. 5,300,318 (Pierre et al.) and Koyama et al., U.S. Patent No. 5,855,914 (Koyama et al.). (*See*, Office Action of January 25, 2006, at pages 3 and 5, hereinafter, "Office Action"). Applicants traverse the rejection as hereinafter set forth.

M.P.E.P. § 706.02(j) sets forth the standard for establishing a *prima facie* case of obviousness as follows:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on

applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).

The Examiner states that Pierre et al. disclose "a process of granulation whereby drug granules are sprayed with a solution of water-soluble drug on a crystal of said water-soluble drug and a further coating with a release control film-coating agent is applied to the drug granule." (*Id.* at page 8). The Examiner further states that Pierre et al. are silent with respect to granular strength but that Applicants have not "demonstrated that the granules produced by Pierre et al.'s process would not have a sufficient or ample strength to be suitable for further coating procedures." (*Id.*). Further, the Examiner posits that one skilled in the art may achieve the suitable or effective granulation strengths through "routine or manipulative experimentation." (*Id.*).

The Examiner also states that although "Koyama et al. do not teach the instant granular strength," either, Koyama et al. do disclose "obtaining stabilized granules that exhibit increased granular strength and . . . cores that are free from granule breakage during the coating process." (*Id.* at page 9).

However, neither cited reference discloses the presently claimed process for achieving substantially higher granular strengths with respect to the drugs selected from "the group consisting of metformin hydrochloride, ethydrionic acid di-sodium, cimetidine, carbocisteine, gabapentin, ciprofloxacin hydrochloride, mexiletine hydrochloride and vancomycin hydrochloride" as currently recited, in part, by claims 1, 3, 7, 10, 12 and 13. Thus, since the cited references do not disclose each and every element of the presently claimed invention, even in combination. (*See, In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991)).

Furthermore, there is no suggestion, or "blazemark" directing the skilled artisan to the selection of the particular compounds recited in the claims. *In re Baird*, 16 F.3d 380, 29 U.S.P.Q.2d 1550 (Fed. Cir. 1994). Thus, the cited references cannot form the basis of a *prima facie* case of obviousness.

Reconsideration and withdrawal of the obviousness rejection of claims 1, 3, 5-7, 9, 10 and 12-14 are respectfully requested.

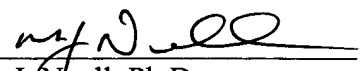
CONCLUSION

If the Examiner has any questions or comments, please contact Thomas J. Siepmann, Ph.D., Registration No 57,374 at the offices of Birch, Stewart, Kolasch & Birch, LLP.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

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Respectfully submitted,

By 
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